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We, the undersigned, Parleclair, 1-3, Boulevard Charles de Gaulle, 92700 Colombes Cedex hereby certify that we are duly authorized to translate the French language, and have produced an accurate and exact translation in English of the French patent : PCT/FR2005/000338 – 11/02/2005, to the best of our translators' knowledge and skill.

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EXPLORATION DEVICE TO MONITOR THE PENETRATION  
OF AN INSTRUMENT IN AN ANATOMIC STRUCTURE

[0001] The present invention refers to the field of spinal surgery.

[0002] In surgery of the spine, for example for pedicular drilling, the bone cortex is often crossed, broken or damaged by the drilling instrument, that may then lead to the poor positioning of the pedicular screws. Following this poor positioning, the pedicular screws, inducing pain, paralysis, haemorrhage, etc. in the patient, may require another surgical intervention or, in certain cases, cause irreparable damage.

[0003] We are familiar with patent application FR2835732, filed by the present applicant, a device to monitor the penetration of an instrument (dill or other type of instrument) in the vertebra by measuring the differences in the electrical impedance during the penetration, so that the practitioner is constantly aware whether the end of the instrument is leaving the bone cortex and penetrating into a zone of soft tissue (marrow, nerves, tissue). In this case, the practitioner modifies the path of the penetration instrument in order to return to the bone cortex.

[0004] Such a device may also be used to detect the formation of a gap in the bone cortex during drilling.

[0005] To facilitate the repositioning of the penetration instrument during a drilling operation (or similar type of operation such as tapping, boring, etc.), but also to enable the proper positioning of the pedicular screw or any other surgical instrument, the practitioner has to know the exact position of the gaps formed during the drilling.

[0006] The present invention therefore aims at proposing an exploration device indicating the position of the gaps formed during a drilling (or similar) operation.

**[0007]** For this purpose, the invention involves, according to its most general acceptance, an exploration device to monitor the penetration of an instrument in an anatomic structure, in particular bone structure, comprising a source of voltage supplying at least two electrodes and a means to measure the impedance between the aforementioned electrodes, and is it remarkable in that the aforementioned device includes a means of angular location formed by at least one electrode punctually coinciding with a peripheral surface of the aforementioned penetration instrument, the coinciding surface of the aforementioned electrode (3) whose position is set off from the longitudinal axis of the aforementioned instrument, as well as a means to detect the position of the aforementioned electrode (3).

**[0008]** By punctual coincidence, we mean a contact surface partially and discontinually coinciding with the peripheral surface of the aforementioned penetration instrument. In particular, an angular contact surface, and by extension a tubular shape are not considered as providing punctual coincidence.

**[0009]** Depending on whether one desires taking lateral readings or readings at the end of the penetration instrument or laterally and at the end, respectively, the penetration instrument will be equipped with at least one electrode coinciding with the lateral surface of the aforementioned penetration instrument and/or at least one electrode coinciding with the peripheral surface of the distal end of the aforementioned penetration instrument.

**[0010]** Advantageously, the aforementioned coinciding electrode is driven in rotation, the aforementioned coinciding electrode being driven at speed of rotation so that it sweeps at least 360 degrees per level of insertion of the aforementioned penetration instrument in the bone structure.

[0011] Preferably, the aforementioned device comprises a plurality of angularly spaced coinciding fixed electrodes and that the means to measure the impedance delivers a signal corresponding to each of the aforementioned electrodes.

[0012] Advantageously, the aforementioned electrodes consist of punctual contacts longitudinally and angularly spaced out.

[0013] Advantageously, the aforementioned electrodes are formed by longitudinal strips.

[0014] According to one specific configuration of the invention, the electrodes are distributed around the longitudinal axis of the penetration instrument.

[0015] Advantageously, the electrodes are symmetrically arranged with respect to the longitudinal axis of the aforementioned penetration instrument.

[0016] Advantageously, the aforementioned electrodes consist of conducting rods of circular, semi-annular, rectangular and/or triangular section. In addition, they may consist of eccentric conducting rods.

[0017] According to the realm of intervention in which the penetration instrument is used, the aforementioned device may comprise at least one electrode at its distal end(s). Advantageously, the aforementioned device comprises two electrodes arranged at the distal end of the aforementioned penetration instrument, the aforementioned electrodes consisting of conducting rods of concentric circular section.

[0018] Advantageously, the aforementioned means of detection consists of visual marking preferably on the handle of the aforementioned exploration device. According to one specific means of creation of the device, the aforementioned handle (6) forms the aforementioned means of detection.

[0019] Advantageously, the aforementioned device also comprises a central channel for the passage of an additional instrument.

[0020] Now, the invention will better be understood using the following description that is only provided for explanatory purposes, with reference to the appended figures:

- figure 1 illustrates a diagram of an exploration device according to the invention;
- figure 2 illustrates a front cutaway view of the distal end of the penetration instrument according to a first configuration of the invention;
- figure 3 illustrates a longitudinal cutaway view of the penetration instrument according to a second configuration of the invention;
- figure 4 illustrates a front cutaway view of the distal end of the penetration instrument according to a third configuration of the invention;
- figure 5 illustrates a perspective view of the penetration instrument according to a fourth configuration of the invention; and
- figure 6 illustrates a longitudinal cutaway view of the penetration instrument according to a fifth configuration of the invention.

[0021] According to the invention, the exploration device (1), illustrated in figure 1, is a device enabling the monitoring of the penetration of an instrument (2) in the bone structures of a human or animal body, the aforementioned structures presenting at least two different zones of electrical impedance.

[0022] The exploration device (1) comprises a source of voltage (not represented) supplying at least two electrodes and a means to measure the impedance (not represented) between the aforementioned electrodes.

[0023] At least one of the aforementioned electrodes is found on the aforementioned penetration instrument (2).

[0024] The aforementioned device also comprises means of signalling producing a signal at the time of detection, by pedometer, a variation of impedance, and therefore the presence of a gap. The aforementioned means of signalling consist of the emission of a visual signal, such as a light, a sound signal, and/or a tactile signal (vibrator, etc.).

[0025] According to one advantageous mode of creation of the invention, the aforementioned device also comprises means for the acquisition and visualisation of the position of the gaps during the penetration of the instrument (2) in the bone structure.

[0026] According to the applications considered, the penetration instrument (2) may either be fixed, or manually driven in rotation by means of drive of the motor type (not represented).

[0027] Therefore, it may consist, in the first configuration, for example of a probe, a square tip, a spatula, a curette or other, and in the second configuration, for example of a screw, a drill, a tap, or other.

[0028] In the following section, the penetration instrument (2) consists of a probe (2). However, the configurations presented are of course applicable to the other penetration instruments mentioned above.

[0029] Figure 2 illustrates the first configuration of the probe (2) forming the aforementioned exploration device (1).

[0030] In this first configuration, the penetration instrument (2) presents two eccentric electrodes (3, 4) of circular section at its distal end, electrode (3) being surrounded but separated from electrode (4) by an insulation ring (5).

[0031] In this example, electrode (3) comprises the positive pole of the aforementioned electronic device, the negative pole of the aforementioned electronic device consisting of the electrode (4). It is obvious that this is only one example of a creation and that the man of the art may create an electronic device whose positive pole consists of the electrode (4) and the negative pole of the electrode (3) without going beyond the invention.

[0032] Each electrode (3, 4) is arranged so as to coincide with the surface of the aforementioned penetration instrument (2).

[0033] To avoid any disturbance of the signal, the surface of the central or internal electrode (3) coinciding with the surface of the aforementioned penetration instrument (2) remains relatively small with respect to the dimensions of the hole made in the bone cortex during the drilling (or other) operation.

[0034] The position of the electrode (3) is detected by specific marking on the aforementioned exploration device (1). Advantageously, the marking is carried out by means of the handle (6) of the aforementioned exploration device (1). It may, for example, consist of a visual signal, for example an arrow, represented on the handle (6). The marking may also consist of any means directly on the handle (6), such as, for example, a specific shape of the aforementioned handle (6).

[0035] Therefore, during the penetration of the instrument (2) in the perforated bone structure, a signal is given off by the aforementioned means of signalling when a variation in impedance measured between the electrodes (3, 4) is detected by the impedometer, indicating the presence of a gap.

[0036] Following this detection, the means of signalling emit a warning signal (visual, sound or tactile). The practitioner then knows that the electrode (3) from the penetration instrument is positioned in front of a gap.

[0037] The practitioner then determines the direction of the gap with the mark corresponding to the position of the electrode (3) marked on the handle (6) of the aforementioned exploration device (1).

[0038] In order to enable full scanning of the bone structure, the aforementioned penetration instrument (2) is endowed with a movement of rotation, the speed of rotation exceeding the speed of progress of the penetration instrument (2) in the bone structure. In other terms, the speed of rotation of the aforementioned instrument (2) is such that the aforementioned penetration instrument (2) sweeps at least 360 degrees by level of penetration.

[0039] Figure 3 illustrates a second configuration of the probe (2) comprising the aforementioned exploration device (1), which enables the detection of gaps laterally arranged with respect to the body of the aforementioned penetration instrument (2).

[0040] In this second configuration, the electrode (3) is positioned in the aforementioned penetration instrument (2) so as to punctually coincide with the lateral surface of the aforementioned penetration instrument (2).

[0041] As for the electrode (4), it is distributed on the rest of the lateral surface of the aforementioned penetration instrument (2), including its distal end. The aforementioned electrodes (3, 4) are separated from each other by an insulant (5).

[0042] The principle of detection and the determination of the direction of the gap are identical to that described above.

[0043] Figure 4 illustrates a third configuration of the probe (2) comprising the aforementioned exploration device (1), which enables detection of gaps arranged at the end of the aforementioned penetration instrument (2).

[0044] In this third configuration, the penetration instrument (2) presents three electrodes (7, 8, 9) of sensibly identical triangular section at the distal end. The aforementioned electrodes (7, 8, 9) distributed around the longitudinal axis of the penetration instrument (2) are angularly spaced. Advantageously, the angular space is identical.

[0045] Since the position of the electrodes (7, 8, 9) is known by the construction, their arrangement on the distal end provides indications about the position of the gaps. In fact, the gap detected will be located between the two electrodes for which a signal is emitted.

[0046] Since the number and triangular shape of the electrodes is given here by way of example, it is understood that the aforementioned penetration instrument (2) may present a greater number of electrodes and a shape other than triangular. The determination of the direction of the gaps is all the more exact when the number of electrodes distributed at the end of the aforementioned instrument (2) is higher.

[0047] Figure 5 illustrates another configuration of the probe (2), enabling detection of the gaps arranged at the end of the aforementioned penetration instrument (2), but also laterally.

[0048] In this configuration, the aforementioned penetration instrument (2) consists of a plurality of electrodes coinciding with the lateral surface of the aforementioned penetration instrument (2) and at the distal end of the aforementioned penetration instrument (2).

[0049] Since the position of each electrode is known, it is then possible, as in the third configuration, to determine the position of the gap by the emission of a signal by the impedometer corresponding to the electrode positioned in front of the gap.

[0050] In the configurations presented above, the means to determine the position of the gaps consist of fixed electrodes. According to a specific configuration of the aforementioned penetration instrument (2) (not represented), the gaps may also be determined by means of one or several mobile electrodes.

[0051] In addition, in the previous examples, the electrodes (3, 4) are respectively carried by the aforementioned penetration instrument (2). Of course, the aforementioned penetration instrument (2) may be equipped with only one electrode (3), the other electrode being positioned on the patient, and more specifically, on a surface other than the surgical wound, without going beyond the field of the invention.

[0052] As specified above, the configurations presented remain applicable to the other penetration instruments mentioned above.

[0053] In particular, in the case where the penetration instrument (2) consists of a drill element, the aforementioned penetration instrument (2) may advantageously comprise at least one electrode (13) coinciding with the lateral surface of the aforementioned penetration instrument (2), as well as two electrodes (10, 11) concentrically arranged at the distal end of the aforementioned penetration instrument (2) (figure 6). It is therefore possible, due to the configuration of the aforementioned penetration instrument (2) to determine the presence and direction of a gap by means of electrodes (11 and 13), as well as prevent any possible perforation of the bone cortex using electrodes (10 and 11). For this purpose, the positioning of a lateral electrode consisting of a rod extending to the distal end should be avoided. If fact, it would be impossible, with such a configuration, to know whether the zone detected by the electrodes is lateral or distal.

**[0054]** The invention is described above by way of example. It is understood that the man of the art is able to create different variants of the invention without going outside of the patent.